Claims 1-6 and 22-24 are deemed by the Examiner to be directed to an elected composition invention and species.

Claims 1-6 and 22-25 have been replaced by claims 26-55 to improve their presentation and define the present invention more clearly over the pertinent prior art.

As to new claims 26-55, claims 26-37 and 41-52 are believed to be directed to the elected composition invention and species, and claims 38-40 and 53-55 are believed to be directed to the non-elected composition species.

Nevertheless, the Examiner is urged to consider all of the new claims 26-55, i.e., including both the elected composition species claims 26-37 and 41-52 and the non-elected composition species claims 38-40 and 53-55, herein as being logically directed to the overall elected composition invention, and to leave production method claims 7-21 for consideration per separate prosecution of the non-elected method invention subject matter in a presently intended division.

Claims 26-28 are akin to claims 1-2, 5 and 6; claims 29-31 are akin to claim 22; claims 32-34 are akin to claim 23; claims 35-37 are akin to claim 24; and claims 38-40 are akin to claim 25, respectively.

Claims 41-55 correspond to claims 26-40 but emphasize the purity of the pertinent composition as being not less than 90%, e.g. as per claim 3.

It is believed that the Examiner's formal criticism (item 3, page 3, of the December 17, 2002 Office Action) as to the manner of

listing of references cited by applicants has been meanwhile overcome by the cumulative submission of the Corrected Information Disclosure Statement dated January 7, 2003, and the 2nd Corrected Information Disclosure Statement dated January 13, 2003.

Applicants concur in the Examiner's interpretation (item 4, page 4, of the December 17, 2002 Office Action) of the skin sensitization incidence concept as claimed herein (see spec., p. 2, line 18, to p. 3, line 2; p. 5, line 22, to p. 6, line 2; and especially p. 9, lines 3-15).

The compositions of the present invention (claims 26-55) concern:

(1) a <u>monoazo metal complex compound</u> containing composition (claims 26-28 and 41-43),

(2) a <u>charge control agent</u> comprising said composition (claims 29-31 and 44-46),

(3) a <u>toner</u> for developing electrostatic images which contains a charge control agent comprising said composition (claims 32-34 and 47-49),

(4) a <u>coloring agent</u> containing said composition (claims 35-37 and 50-52), and

(5) a <u>colored thermoplastic resin composition</u> containing said composition as a coloring agent (claims 38-40 and 53-55),

in each case with said composition having a <u>skin sensitization incidence of not more than 20%</u>, in a skin sensitization potential test based on the maximization method (claims 26-55).

In particular, the <u>purity</u> of the monoazo metal complex compound of said composition is <u>not less than 90%</u>, as determined by high performance liquid chromatography (HPLC) (claims 41-53).

More specifically, the monoazo metal complex compound of said composition is of formula (1) as accordingly defined herein (claims 27-28, 30-31, 33-34, 36-37, 39-40, 42-43, 45-46, 48-49, 51-52 and 54-55).

The non-elected methods for producing the monoazo metal complex compound containing compositions of the present invention concern the use of an alcoholic organic solvent for removing the pertinent impurity substances therefrom (claims 7-21).

Skin sensitization and allergy and human safety considerations as regards monoazo metal complex compound containing compositions as contemplated herein have become important, given the present day pervasive use of such compounds and common exposure of human beings thereto (spec., p. 1, line 17, to p. 3, line 19).

A basic problem is that, <u>because of the production method</u> used conventionally to form these metal complex compounds, they are <u>contaminated by impurity substances traceable to starting materials and by products</u>, and by impurity substances <u>associated with metallization</u>, which impurity substances <u>cause undesired skin sensitization effects</u> (spec., p. 3, lines 20-23).

By way of the present invention, this skin sensitization problem is overcome by removing such impurity substances using an alcoholic organic solvent, whereby the skin sensitization incidence

in said skin sensitization potential test, based on the maximization method, of the given composition is not more than 20%, and desirably the purity of the monoazo metal complex compound is not less than 90%, accordingly providing a <u>high degree of safety</u> to humans exposed thereto plus other advantages, e.g., as regards the charge control agent, toner, coloring agent and colored thermoplastic resin composition aspects herein (spec., p. 4, line 1, to p. 7, line 6; p. 9, line 16, to p. 10, line 17; p. 15, line 9, to p. 16, line 20; and p. 20, line 7, to p. 21, line 11).

Reconsideration is requested of the rejection of the present invention as unpatentable, i.e., as anticipated under 35 USC 102 for lack of novelty by, or alternatively as obvious under 35 USC 103 over, each of:

Onuma et al., U.S. 6,426,169 issued July 30, 2002, based on a U.S. filing date of October 30, 2000 (Onuma 169); and

Okubo et al., U.S. Patent Publication 2001/0004667 A1, based on a U.S. filing date of December 5, 2000, and published June 21, 2001 (Okubo 667).

The accompanying certified English translations of both (1) the first Japanese Priority Application No. 2000 - 163222 dated May 31, 2000, and the (2) second Japanese Priority Application No. 2001 - 114208 dated April 12, 2001, being hereby filed herein under 37 CFR 1.131, make clear that the concept of the present invention, as established by the <u>first said priority application of May 31, 2000</u>, even without the second said priority application of April 12,

2001, predates the effective dates of each of Onuma 169 and Okubo 667.

Hence, Onuma 169 and Okubo 667 are not valid references herein, whereupon the 35 USC 102 anticipation rejection, or in the alternative 35 USC 103 obviousness rejection, on each of said references should be withdrawn as unwarranted under the circumstances.

Nevertheless, on the merits, it will be noted that Onuma 169 recognizes the problem of impurity chemicals contaminating metal complexes of azo dyes used as charge control agents (col. 1, lines 46-56), and of amorphous metal complex salts of monoazo compounds causing toners containing them to stick onto the associated photosensitive member (col. 1, line 63, to col. 2, line 10), yet only concerns toner particles containing a monoazo iron compound and having a tetrahydrofuran (THF) soluble content providing a gel-permeation chromatogram with specific molecular weight region peaks having nothing to do with the skin sensitization and purity characteristics of the compounds contemplated by the instant invention.

The Onuma 169 production process involves reacting an appropriate monoazo compound with an iron source compound in an aqueous and/or organic solvent, e.g., with the reaction product as formed in the organic solvent being dispersed in water and the resulting precipitate filtered, washed with water and dried (col. 13, lines 27-34). In addition to water, the contemplated organic solvents as reaction medium include water miscible organic

solvents, alcohols, ethers or glycols; and non-protonic polar solvents (col. 13, lines 35-45), with ethylene glycol monomethyl ether (i.e., methyl cellosolve), ethylene glycol monoethyl ether (i.e., ethyl cellosolve) and ethylene glycol being preferred (col. 13, lines 46-50).

Onuma 169 does not consider alcoholic organic solvents, as opposed to aqueous solvents or non-protonic polar solvents, to be critical as reaction medium or purifying procedure recovery solvent in the manner of the present invention, and such reference is <u>conspicuously incomplete as to production process and purifying procedure details</u>, cf. <u>Production Ex. 1</u> (col. 26, lines 50-67), thus <u>preventing a meaningful comparison of the present invention therewith</u>.

Onuma 169 does not concern the production and use of a monoazo metal complex compound containing composition whose incidence of skin sensitization is not more than 20%, and especially whose purity is not less than 90%, in the manner of the invention.

Onuma 169 would teach the artisan nothing about the concept of the present invention and is completely inapposite hereto.

Okubo 667 recognizes the environmental safety concerns that attend use of iron complex compounds in toners for electrostatic image development (p. 1, col. 1, #[0010]), but only provides am organic metal complex compound of an <u>electroconductivity of at most 100 μS/cm</u> in ion exchanged water (p. 1, col. 2, #[0013] - #[0014]; and p. 2, col. 2, #[0020]), and having nothing to do with safety concerns, nor with the production of a monoazo metal complex

compound containing composition whose incidence of skin sensitization is not more than 20%, let alone of a purity of not less than 90%, as contemplated herein.

Instead, Okubo 667 concerns the corelationship between a stable image density and an electroconductivity, subject to the adverse effects caused by the presence of inorganic salt by products (p. 2, col. 2, to p. 3, col. 1, #[0022]).

It is significant that the Okubo 667 production process and production examples give no specific details, cf. Preparation Exs. 1-2 (p. 4, col. 1, #[0025] - #[0026]; and p. 15, col. 1, #[0158] - #[0159]); thus preventing a meaningful comparison of the present invention therewith.

Okubo 667 does not concern the production and use of a monoazo metal complex compound containing composition whose incidence of skin sensitization is not more than 20%, and especially whose purity is not less than 90%, in the manner of the present invention, and would teach the artisan nothing about the instant concept, and thus is completely inapposite hereto.

Withdrawal of the anticipation rejection, and alternatively of the obviousness rejection, on each of Onuma 169 and Okubo 667, is respectfully urged.

Reconsideration is requested of the rejection of the present invention as unpatentable, i.e., as anticipated under 35 USC 102 for lack of novelty by, or alternatively as obvious under 35 USC 103 over, each of:

Ookubo et al., U.S. 6,120,958 issued September 19, 2000, based on a U.S. filing date of July 30, 1999 (Ookubo 958); and

Sukata et al., U.S. 5,843,611 issued December 1, 1998 (Sukata 611).

Ookubo 958 notes the problem of environmental safety as to chromium compound containing charge control agents compared to iron compound containing charge control agents (col. 1, lines 47-54), and uses a chromium compound-excluding toner having an azo type iron complex as charge control agent, but is limited to a 6-15 μm volume average particle size range (col. 2, lines 1-11), since the compound as obtainable per the known method has a 10-100 μm particle size distribution which poorly functions as a charge control agent. The desired smaller size range is obtained by recrystallization from an unspecified organic solvent of the coarsely sized original product (col. 9, lines 24-35 and 41-49).

In Ookubo 958, there is no indication of any significance of skin sensitization, let alone purity, factors in the manner of the present invention.

It cannot be overemphasized that the dissolving of the already obtained coarsely sized product in the unspecified organic solvent followed by recrystallization therefrom per Ookubo 958 (col. 9, lines 41-49) is for the purpose of downwardly chemically adjusting the volume average particle size, akin to physically pulverizing such coarsely sized product in a sand grinder mill followed by classification for the same purpose.

Such Ookubo 958 recrystallization based chemical size-adjusting step is not concerned with purification of the monoazo metal complex compound in question, but only with size reduction, and indeed Ookubo 958 makes no mention of selecting any particular organic solvent for such recrystallization based chemical size-adjusting step nor that use of such organic solvent results in the purification of the desired monoazo metal complex compound in the manner of the present invention.

Per Ookubo 958 Preparation Ex. 1 (col. 13, lines 5-46), the azo type iron complex compound of formula C (col. 3, lines 1-21) is formed by initial coupling reaction in an aqueous system, with the resulting monoazo compound being isolated, and a paste thereof, of unstated amount, then being dispersed in a 3:1 ratio water/ethylene glycol mixture by weight (150 parts water: 50 parts ethylene glycol, i.e., 3 times as much water as alcoholic organic solvent) along with 10 parts by weight of sodium hydroxide and 11 parts by weight of salicylic acid and sodium acetate, plus a 38% ferric chloride solution for metallizing.

Upon metallization, the iron complex compound sodium salt precipitate formed is recovered by filtration as a paste of unstated amount, which is then dispersed in a 6:1 ratio water/ethyl alcohol mixture by weight (300 parts water: 50 parts ethyl alcohol, i.e,, 6 times as much water as alcoholic organic solvent) along with 10 parts by weight of ammonium sulfate to obtain 40 parts by weight of an ammonium iron complex per said formula C, without any indication of its yield or purity. The amount of sodium salt paste

recovered and used to form the ammonium iron complex of said formula C is unknown, and thus no meaningful comparison with the instant invention is possible.

It is clear from Ookubo 958 Preparation Ex. 1 that since 3 times as much water as alcoholic organic solvent is used in producing the monoazo complex compound sodium salt, the paste collected by filtration perforce includes a large portion of impurities formed in the metallization.

In turn, it is also clear from Ookubo 958 Preparation Ex. 1 that since 6 times as much water as alcoholic organic solvent is used in producing the ammonium salt from the sodium salt, the cake collected by filtration perforce also includes a large portion of impurities.

It is believed to be self-evident that these impurities in the sodium salt paste and in the ammonium salt cake per Ookubo 958 Preparation Ex. 1 will not be removed by washing with water thereafter, due to the hydrophobic character of such impurities.

As will be seen below, in connection with the discussion of the accompanying Declaration Under 37 CFR 1.132 (132 Declaration), the impurities content of the resulting Ookubo 958 product by percentage is believed to be at about the same level as that of Composition D thereof (water/alcoholic organic solvent workup step). Hence, the azo type iron complex compound described in Ookubo 958 perforce does not have similar properties to those of the monoazo metal complex compound of the present invention.

Accordingly, Ookubo 958 confirms the technical prejudice of Onuma 169 and Okubo 667 in not recognizing the importance of using an alcoholic organic solvent to remove attendant impurity substances sufficiently to form a product with an incidence of skin sensitization of not more than 20%, and especially a purity of not less than 90%, in the manner of the present invention. Instead, Ookubo 958, like both Onuma 169 and Okubo 667, fails to set forth specific details of monoazo metal complex compound production, or use of an alcoholic organic solvent in particular therein, whereby to provide a degree of impurity substance contamination removal, pertinent to the instant invention.

Ookubo 958 would teach the artisan nothing about the concept of the present invention and is completely inapposite hereto.

Sukata 611 concerns monoazo metal complex compounds usable as charge control agents in toners, which compounds are formed by metallizing in water and/or an organic solvent, but recovered by dispersing the reaction product of the metallization reaction in water, collecting the precipitate by filtration, washing the precipitate with water and then drying it (col. 10, lines 44-54).

In Sukata 611, organic solvents useful for the metallizing reaction include water soluble organic solvents including alcohol series, ether series, and glycol series organic solvents (such as ethanol, methanol, ethylene glycol monomethyl ether, ethylene glycol monoethyl ether..., ethylene glycol and propylene glycol), and aprotic polar solvents (such as N,N-dimethyl formamide), preferably ethylene glycol monomethyl ether (methyl cellosolve),

ethylene glycol monoethyl ether (ethyl cellosolve) and ethylene glycol (col. 10, line 55, to col. 11, line 10).

On the other hand, the Sukata 611 metallization reaction product is recovered by dispersing it in water and collecting the precipitate by filtration. There is no teaching in Sukata 611 of recovering the metallization reaction product using an alcoholic organic solvent in the manner of the present invention.

Sukata 611 notes that isolation of the reaction products is difficult even when various chromatographies are attempted (col. 11, lines 23-27). However, Sukata 611 makes no mention of purification of the monoazo metal complex compound in question.

Thus, in Sukata 611 Ex. 1 (col. 16, lines 25-47), the metallization reaction mixture of 110 g (0.59 mol; mol. wt = 187) of chromium (III) formate and 415 g (1.39 mol; calc. mol. wt = 298.5) of the example monoazo compound (1) (col. 7, lines 55-65), in an organic system formed of a mixture of 620 g ethyl cellosolve and 380 g ethylene glycol, is dispersed while hot, i.e., at 125°C, in an aqueous system formed of 4000 ml of a 3% aqueous HCl solution, and the resulting mixture after being stirred while hot, i.e., at 60°C, for 1 hour is filtered, and the cake formed is washed with water and dried to yield 400 g of a purple powder.

The Sukata 611 Ex. 1 purple powder includes:

a 3:2 type example monoazo metal compound (a) (col. 12, lines 42-60), which is a major reaction product,

a 2:1 type example monoazo metal compound (1), which is accordingly at best a minor reaction product, and

unreacted example monoazo compound (1) (col. 7, lines 53-65).

Such inherently significantly contaminated impurity substance containing purple product of Sukata 611 Ex. 1 does not suggest production of a product having a skin sensitization incidence of not more than 20%, let alone having a purity of not less than 90%, in the manner of the present invention.

Sukata 611 Exs. 2-4 are similar to Sukata 611 Ex. 1, in that after metallization of the monoazo compound, the products formed are collected by filtration and washed with warm or hot water, but such washing action is clearly insufficient to remove any significant amount of impurities formed during the metallization.

As will be seen below, in connection with the discussion of the accompanying 132 Declaration, the impurities content of the Sukata 611 Exs. 1-4 products by percentage are believed to be at about the same level as that of Composition C (water workup step) of said 132 Declaration and of Comparative Ex. 1 herein. Hence, the monoazo iron complex compounds described in Sukata 611 Exs. 1-4 perforce do not have similar properties to those of the monoazo metal complex compound of the present invention.

As to Sukata 611 Ex. 5 (col. 18, lines 5-33), the metallization reaction mixture of 76.0 g (0.41 mol; mol. wt = 187) of chromium (III) formate, 24 g urea and 228 g (0.76 mol; calc. mol. wt = 298.5) of the example monoazo compound (1) (col. 7, lines 55-65), in an organic system formed of a mixture of 340 g ethyl cellosolve and 220 g ethylene glycol, is filtered while hot, i.e., at 130°C, and the filtrate is dispersed in an aqueous system formed

of 30 g of a 35% HCl solution in 2000 ml of water, and after stirring at 50-69°C for 30 minutes the resulting mixture is filtered, the cake formed is washed with water and dried to yield 220 g of a blackish purple powder.

Then, 81 g of the blackish purple powder are washed with methanol using a Soxhlet extractor and dried to yield 71 g of a blackish brown powder, without any indication of the extractor treatment time, operating temperature, flow rates and proportions of attendant ingredients, etc., obviously because this workup step is not for the purpose of purification of the product to a particular level.

The Sukata 611 Ex. 5 blackish brown powder includes:

a 6:4 type example monoazo metal compound (g) (col. 14, lines 15-28), which is a major reaction product, and

very small amounts of:

a 3:2 type example monoazo metal compound (a) (col. 12, lines 42-60), and

a 2:1 type example monoazo metal compound (1) (col. 7, lines 53-65).

Such inherently significantly contaminated impurity substance containing purple product of Sukata 611 Ex. 5 does not suggest production of a product having a skin sensitization incidence of not more than 20%, let alone having a purity of not less than 90%, in the manner of the present invention.

Since Sukata 611 Ex. 5 gives no indication of the Soxhlet extractor treatment conditions such as operating time, temperature,

flow rates and proportions of attendant ingredients, etc., <u>no meaningful comparison with the instant invention is possible</u>.

In any case, as a practical matter, since the Sukata 611 Ex. 5 resulting product contains only a very small amount of the 2:1 type example monoazo metal compound (1), it can hardly be said that the skin sensitization incidence of such 2:1 type example monoazo metal compound is not more than 20%, or that its purity is not less than 90% in the manner of the present invention.

Sukata 611 confirms the technical prejudice of Onuma 169 and Okubo 667, as well as of Ookubo 958, in not recognizing the importance of using an alcoholic organic solvent to remove attendant impurity substances sufficiently to form a product with an incidence of skin sensitization of not more than 20%, and especially a purity of not less than 90%, in the manner of the present invention. Instead, Sukata 611, like both Onuma 169 and Okubo 667, as well as Ookubo 958, <u>fails to set forth specific details</u> of monoazo metal complex compound production, or use of an alcoholic organic solvent in particular therein, whereby to provide a degree of impurity substance contamination removal, pertinent to the instant invention.

The mere fact that Sukata 611 Ex. 5 uses a Soxhlet extractor after-treatment with methanol is of no consequence, since no details are given as to the operating conditions, preventing a meaningful comparison test to be undertaken, as aforesaid.

Sukata 611 would teach the artisan nothing about the concept of the present invention and is completely inapposite hereto.

As to the accompanying 132 Declaration, the Synthesis of monoazo dye step (first step) generally corresponds to instant Ex. 1 (a), but on a 0.4 mol basis rather than a 0.2 mol basis as in Ex. 1, and the same is true of the Synthesis of monoazo metal complex compound step (second step) as compared to instant Ex. 1 (b). The aqueous dispersion liquid obtained per said second step is filtered to obtain a wet cake, which is divided into quarters, i.e., wet cakes A, B, C and D, used to form corresponding workup compositions A, B, C and D, of HPLC determined purity noted in Table 1.

Wet cake A was dried at 100°C, and the black product obtained was milled to yield 31.0 g (100% yield as control; at only 81.3% purity) of monoazo metal complex compound containing composition, designated Composition A, i.e., per no purification workup.

Wet cake B was dried at 100°C, and 31.0 g of the black product obtained were dispersed in 80 g of methanol, stirred at 60°C for 1 hour, cooled to 30°C, filtered, further washed with 20 g of methanol and dried at 50°C under reduced pressure to yield 28.1 g (28.1/31.0 = 90.6% yield based on Composition A; at 95.1% purity) of monoazo metal complex compound containing composition, designated Composition B, i.e., per the present invention alcoholic organic solvent work up.

Wet cake C was dispersed in 750 ml of water, stirred at 60°C for 1 hour, filtered, further washed with 50 ml of water and dried at 100°C, and the black product obtained was milled to yield 30.2 g (30.2/31.0 = 97.4% yield based on Composition A; at only 83.4%

purity) of monoazo metal complex compound containing composition, designated Composition C, i.e., per the prior art water work up.

Wet cake D was dispersed in a 5:1 ratio mixture of 200 ml of water and 40 g of ethanol (200/40 = 5 times as much water as alcoholic organic solvent), stirred at room temperature for 1 hour, filtered, washed with 50 ml of water and dried at 100°C, and the black product obtained was milled to yield 29.5 g (29.5/31.0 = 95.2% yield based on Composition A; at only 87.8% purity) of monoazo metal complex compound containing composition, designated Composition D, i.e., akin to the prior art water/alcoholic organic solvent mixture work up.

As noted above, it is believed that the Ookubo 958 product impurities content is by percentage at about the same level as that of Composition D, and hence the azo type iron complex compound described in Ookubo 958 does not have the same properties as those of the monoazo metal complex compound of the present invention.

It is likewise believed that the Sukata 611 Exs. 1-4 product impurities content is by percentage at about the same level as that of Composition C and Comparative Ex. 1 herein, i.e., per the prior art water work up, and hence the monoazo metal complex compounds thereof are unlike the monoazo metal complex compound contemplated by the present invention. However, since Sukata 611 Ex. 5 omits critical details as to the Soxhlet extractor work up for methanol washing of the monoazo metal complex compound product, which results in a mixture of compounds, and thus is not concerned with purification, it perforce fails to suggest the instant concept.

It will be seen from the 132 Declaration, with respect to purity increase consequent product work up, that as between Composition C and Composition A (control), use of water work up shows only a 2.6% purity increase (83.4 - 81.3 = 2.1; 2.1/81.3 = 2.6%) over no work up (control), and that as between Composition D and Composition A, use of water/alcoholic organic solvent mixture, shows an 8% purity increase (87.8 - 81.3 = 6.5; 6.5/81.3 = 8%) over no work up. On the other hand, as between Composition B and Composition A, use of alcoholic organic solvent shows an unexpectedly high 17% purity increase (95.1 - 81.3 = 13.8; 13.8/81.3 = 17%) over no work up.

It will be further seen from the 132 Declaration, with respect to purity increase consequent product work up, that as between Composition C and Composition D, use of water/alcoholic organic solvent mixture shows only a 5.3% purity increase (87.8 - 83.4 = 4.4; 4.4/83.4 = 5.3%) over use of water, and that as between Composition B and Composition D, use of alcoholic organic solvent shows an 8.3% purity increase (95.1 - 87.8 = 7.3; 7.3/87.8 = 8.3%) over use of water/alcoholic organic solvent mixture. On the other hand, as between Composition B and Composition C, use of alcoholic organic solvent shows a unexpectedly high 14% purity increase (95% - 83.4 = 11.7; 11.7/83.4 = 14%) over water.

In contrast thereto, it will be noted from the 132 Declaration, with respect to yield decrease consequent product work up, that as between Composition C and Composition A (control), use of water work up shows a -2.6% yield decrease (31.0 - 30.2 = 0.8;

0.8/31.0 = -2.6%) compared to <u>no work up</u> (control), and that as between Composition D and Composition A, use of water/alcoholic organic solvent <u>mixture</u> shows a <u>-4.8% yield decrease</u> (31.0 - 29.5 = 1.5; 1.5/31.0 = -4.8%) compared to <u>no work up</u>. On the other hand, as between Composition B and Composition A, use of <u>alcoholic organic solvent</u> shows a <u>-6.1% yield decrease</u> (31.0 - 28.1 = 1.9; 1.9/31.0 = -6.1%) compared to <u>no work up</u>.

Since Ookubo 958 and Sukata 611 are not particularly concerned with high purity, let alone with skin sensitization incidence considerations, but instead with other considerations as to the products there discussed, and since yield is always a commercially important factor, the skilled artisan would normally seek to maximize yield during work up phase of production, and thus would favor use of water work up and at worst use of water/organic solvent mixture work up, but certainly not use of alcoholic organic solvent alone in the manner of the present invention.

It is only upon becoming aware of the instant concept, in which the incidence of skin sensitization is to be kept at not more than 20%, that the need for high purity becomes of significance.

It is clear from the present disclosure taken with the prior art as exemplified by the cited references that, in general, a product containing a monoazo metal complex compound is <u>washed with water to remove</u> mainly <u>water soluble</u> salts, such that <u>hydrophobic impurities</u> are <u>difficult to remove</u>.

However, according to the present invention, removal of impurities formed in the metallization process is efficiently

attained by using an alcoholic organic solvent, instead of water, in the purification process of the monoazo metal complex compound.

Thus, in Ex. 1 of the present invention, it is believed that crystallized impurities are included in the monoazo metal complex compound containing composition prepared per procedure (b), i.e., Synthesis of monoazo metal complex compound. These impurities which exert an adverse influence on skin sensitization characteristics are removed with methanol per procedure (c), i.e., Purification process.

On the other hand, in Ex. 2 of the present invention, the monoazo dye is metallized in ethylene glycol monoethyl ether, and a wet cake is separated from the reaction mixture by filtration. Because the noted impurities are not crystallized in the reaction mixture, but rather remain dissolved in the attendant ethylene glycol monoethyl ether, they are removed from the wet cake.

Fundamentally, Ex. 1 (b) herein shows the metallization of 62 g of the monoazo dye at 130°C in alcoholic organic solvent, dispersing the reaction mixture while still hot, i.e., at 90°C, in aqueous HCl, filtering the resulting precipitate, washing it with water and drying it at 100°C to form 60 g of non-purified product. There is no intervening step of cooling the hot alcoholic organic solvent based reaction mixture from a high temperature, e.g., 90°C, to a low temperature, e.g., 30°C, and filtering off the resulting precipitate of the desired product from the impurities which remain dissolved at such low temperature in the reaction mixture, before dispersing the desired product in the aqueous HCl.

Hence, a separate purification after-step is effected in Ex. 1 (c) by dispersing the 60 g of non-purified product in hot, i.e., 63°C, alcoholic organic solvent, then cooling, e.g., to 30°C, filtering off the wet cake of desired product, washing it with alcoholic organic solvent, and drying it at 50°C under reduced pressure to provide 56.4 g of purified product having a 10% skin sensitization incidence and a 94.3% purity. Per this purification after-step, the impurities remain dissolved in the alcoholic organic solvent at the cooled temperature, e.g., 30°C, while the desired product precipitates from such solvent.

On the other hand, in Ex. 2 herein, which generally involves a combination of Ex. 1 (b) and Ex. 1 (c), 62 g of the monoazo dye is metallized at 130°C in alcoholic organic solvent, the hot reaction mixture is cooled, i.e., to 30°C, and while the impurities remain dissolved in the alcoholic organic solvent, the desired product precipitates therefrom, and is filtered, washed with water, and then dispersed in aqueous HCl, whereupon the resulting precipitate of the desired product is filtered, washed with water and dried at 100°C to form 56.6 g of purified product having a 10% skin sensitization incidence and a 95.9% purity.

Per this Ex. 2 combination metallization and purification step, the impurities remain dissolved in the alcoholic organic solvent based reaction mixture at the cooled temperature, e.g., 30°C, while the desired product precipitates from such solvent, i.e., prior to aqueous HCl treatment.

In contrast thereto, per Comparative Ex. 1 herein, 62 g of the monoazo dye are metallized in alcoholic organic solvent at 130°C, the reaction mixture is cooled to a still hot temperature, i.e., 90°C, and dispersed in aqueous HCl, and the resulting precipitate is filtered off, washed with water and dried at 100°C to yield 60 g of non-purified product having a detrimental 90% skin sensitization incidence and an inefficient 82.8% purity.

Per Comparative Ex. 1, there is no intervening step of cooling the hot alcoholic organic solvent based reaction mixture from a high temperature, e.g., 90°C, to a low temperature, e.g., 30°C, and filtering off the resulting precipitate of the desired product from the impurities which remain dissolved at such low temperature in the reaction mixture, before dispersing the desired product in the aqueous HCl.

Per Comparative Ex. 2 herein, which involves a comparative purification step, analogous to that of Ex. 1 (c), 50 g of the non-purified product from Comparative Ex. 1 are dissolved in alcoholic organic solvent, refluxed at 63°C, and the reaction mixture cooled to a cool temperature, i.e., 30°C, whereupon the resulting precipitate is filtered off, while the resulting alcoholic organic solvent based filtrate is dispersed in aqueous HCl, and the resulting precipitate is filtered off from the aqueous HCl system, washed with water and dried at 100°C to yield only 3.4 g of still non-purified product having a detrimental 100% skin sensitization incidence and an inefficient 27.8% purity.

Table 1 herein shows the low 10% skin sensitization incidence and high 94.2-95.9% purity achievable in the desired product per Exs. 1-2 according to the present invention, compared to the high 90-100% skin sensitization incidence and low 82.8-27.8% purity achievable per Comparative Exs. 1-2.

Consonant therewith, Table 1 of the 132 Declaration shows the similar high 95.1% purity at an acceptably high 90.6% yield (28.1/31.0 = 90.6%) per Composition B achievable in the desired product according to the present invention, compared to only an 83.4% purity at a 97.4% yield (30.2/31.0 = 97.4%) per Composition C achievable in the desired product using a water wash work up, and to only an 87.8% purity at a 95.2% yield (29.5/31.0 = 95.2%) per Composition D achievable in the desired product using a water/organic solvent mixture wash work up.

Since the prior art as exemplified by the cited references herein is silent as to the need for low skin sensitization and high purity characteristics for the desired product, and since such references fail to set forth sufficient production process and work up recovery details for the compounds in question to permit direct comparison of the instant invention therewith, it cannot reasonably be presumed, i.e., at applicants' expense, that the desired purified product of the present invention is the same as or is taught by any of such references.

Moreover, given the industrial scale commercial economics fundamentally involved in this field of endeavor, it is plausibly and reasonably to be presumed that the production process and work

up recovery activities of the cited references are concerned with the achieving of high yields as opposed to high purities at the expense of high yields of the desired products. This would lead the skilled artisan away from the concept of the present invention, rather than teach it.

There is clearly no relationship shown herein between the Ookubo 958 product having a critical volume average particle size range of 6-15 μm, which excludes 2 μm and 20 μm particle sizes (Ookubo 958 Ex. 1 compared to Comparative Exs. 1-2; and Table 1), and the instant product having a skin sensitization incidence of not more than 20%, and desirably a purity of not less than 90%.

Likewise, there is clearly no relationship shown herein between the Sukata 611 product with respect to which high purity is clearly not attainable (Sukata 611 Exs. 1-5, especially col. 16, lines 42-47; col. 17, lines 19-24 and 44-48; and col. 18, lines 1-4 and 25-32), and the instant product having a skin sensitization incidence of not more than 20%, and desirably a purity of not less than 90%.

In view of the foregoing, withdrawal of the anticipation rejection, and alternatively of the obviousness rejection, on each of Ookubo 958 and Sukata 611, is respectfully urged.

It is submitted that Onuma 169, Okubo 667, Ookubo 958 and Sukata 611, each alone or together in any combination, only become meaningful by unfair hindsight consideration of the present invention in the light of the instant disclosure itself to show the way.

In point of fact, even if the instant monoazo metal complex compounds were to be shown to have similar charge control characteristics to the monoazo metal complex compounds of each of Onuma 169, Okubo 667, Ookubo 958 and Sukata 611, this would not thereby mean that such reference compounds would perforce be presumed to possess the same (or similar) skin sensitization incidence and purity characteristics to those of the instant compounds.

This is especially true in the present situation, because <u>no relationship</u> has been shown to exist <u>in this field of art between charge control characteristics</u> of monoazo metal complex compounds, on the one hand, <u>and skin sensitization incidence and purity characteristics</u> of such monoazo metal complex compounds, on the other hand.

Indeed, it is impermissible for the Examiner to hold tacitly that the inherent features and advantages of the invention in question are relevant to obviousness and somehow demonstrate that the invention is obvious, since inherency of an advantage and its obviousness are entirely different questions. <u>In re Spormann</u>, 150 USPQ 449, 452 (1966); <u>In re Adams</u>, 148 USPQ 742, 745-746 (1966).

It is submitted that the invention per claims 26-55 is both novel and unobvious, and thus patentable, over the prior art as typified by the references of record herein.

The non-elected subject matter is intended to be prosecuted by way of one or more divisional applications in due course.

Reconsideration and allowance are respectfully requested.

Favorable action is most earnestly solicited.

Respectfully submitted
for applicant,

By *Peter James Franco*

Peter James Franco
Reg. No. 17,957
For McGlew and Tuttle
Scarborough Station
Scarborough, NY 10510-0827
(914) 941-5775

PJF/E

Dated: *May 16, 2003*

IF THIS RESPONSE IS CONSIDERED FILED OUTSIDE A SHORTENED STATUTORY PERIOD SET OR NON-STATUTORY PERIOD, THE COMMISSIONER OF PATENTS AND TRADEMARKS IS HEREBY PETITIONED FOR AN EXTENSION OF TIME UNDER 37 CFR 1.136 (a) AND HEREBY AUTHORIZED TO CHARGE THE FEE REQUIRED, FOR THIS RESPONSE TO BE CONSIDERED TIMELY, TO OUR DEPOSIT ACCOUNT NO. 13-0410.

SHOULD ANY OTHER FEE BE REQUIRED, SUCH FEE IS HEREBY REQUESTED TO BE CHARGED TO SAID DEPOSIT ACCOUNT NO. 13-0410.

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS EXPRESS MAIL IN AN ENVELOPE ADDRESSED TO: HON. COMMISSIONER OF PATENTS AND TRADEMARKS, WASHINGTON, D.C. 20231,

RECEIPT NO. *EV323628857US* ON *May 16, 2003*

BY: *[signature]* *May 16, 2003*

MAIL CLERK DATE

Marked-up version of page 26

polymerization catalyst, polymerize this mixture into a desired crystalline thermoplastic resin, and mold this resin by an appropriate method. Molding can be achieved by any molding methods in common use, including injection molding, extrusion molding, compression molding, foaming molding, blow molding, vacuum molding, injection blow molding, rotational molding, calendering and solution casting

EXAMPLES

The present invention is hereinafter described in more detail by means of the following examples, which are not to be construed as limitative. In the description below, "part(s) by weight" is referred to as "part(s)".

Examples 1 and 2 and Comparative Examples 1 and 2 concern the production of the monoazo metal complex compound containing composition of the present invention.

Example 1

(a) Synthesis of monoazo dye

Water 300 ml

Hydrochloric acid 20.0 g

4-chloro-2-aminophenol 28.6 g

After an aqueous solution comprising the above ingredients was cooled to 5°C, a solution of 14.0 g of sodium nitrite in 60 ml of water was added to the solution drop by drop over a period of 30 minutes. This mixture was stirred at 5 to 15°C for 1 hour, after which the reaction mixture was filtered, to yield an aqueous solution of the diazonium salt of 4-chloro-2-aminophenol (solution A).

Water 400 ml

Marked-up version of page 27

Sodium hydroxide 14.0 g

2-naphthol 28.8 g

Subsequently, the aforementioned solution A was added drop by drop over a period of 40 minutes to an aqueous solution of the ingredients shown above, after which this mixture was stirred for 3 hours. The precipitated reaction product was collected by filtration, washed with water, and dried at 100°C, to yield 62.0 g of 1-(5-chloro-2-hydroxyphenyl)azo-2-hydroxynaphthalene (monoazo dye).

(b) Synthesis of monoazo metal complex compound

Monoazo dye obtained in (a) 62.0 g

Chromium formate 19.2 g

Ethylene glycol monoethyl ether 200 g

After the above ingredients were mixed and stirred at 130°C for 6 hours, this mixture was cooled to 90°C, and the reaction mixture was dispersed in an aqueous solution of 15 g of hydrochloric acid in 200 ml of water. The solid was separated from this dispersion by filtration and washed with 1200 ml of water, after which it was dried at 100°C. The black product obtained was milled to yield 60 g of a non-purified monoazo metal complex compound (composition containing a monoazo metal complex compound).

(c) Purification process

60 g of the non-purified monoazo metal complex compound (composition containing a monoazo metal complex compound) was dispersed in 120 g of methanol and stirred at 63°C for 1 hour, after which it was cooled to 30°C and filtered through Toyo Filter Paper No. 2. The wet cake obtained was further